UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE OPINIONS OF PHILIP RUSS

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Pursuant to Federal Rules of Evidence 702 and 703, Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis Pharma, Inc., Actavis LLC, Torrent Pharmaceuticals Ltd., Torrent Pharma Inc., Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare US, LLC (collectively, "Defendants") submit this Reply Memorandum of Law in Support of Defendants' Joint Motion to Exclude Opinions of Philip Russ ("Motion").

INTRODUCTION

Plaintiffs' response opposing Defendants' Motion (ECF No. 2331, "Opposition") ignores the bedrock reason this Court should exclude Russ's opinions – he premised his analysis and conclusions with respect to the Finished Dose Defendants (Teva and Torrent) on fundamental assumptions that are demonstrably false. Whether Russ should have reviewed or credited certain documents over others may well be a matter for cross-examination, but the fact that he based *the entirety of his expert report* on false assumptions renders his opinions so unreliable that they cannot reach the jury under *Daubert*. Russ's approach of making assumptions on the basis of the material picked for him to review by Plaintiffs' counsel and drawing sweeping conclusions based on the lack of certain information, then pivoting to entirely new arguments when confronted with contradictory evidence, reflects an absence of any discernible, let alone reliable, methodology in forming his opinions.

Plaintiffs effectively concede that Russ should not be permitted to comment on Torrent's state of mind, and their attempt to recharacterize his opinions as statements of "fact" should be rejected. Plaintiffs ignore Russ's clear testimony that he is, in fact, opining on Torrent's motivations. Moreover, the plain language of Russ's opinions makes it clear that they are not statements of "fact," but rather improper opinions on motive, intent, and state of mind.

Finally, plaintiffs cannot refute that Russ did not disclose or provide support for the opinion that ZHP's valsartan API was adulterated in his expert report – and repeatedly disclaimed offering such an opinion at his deposition. While plaintiffs assert that Russ merely intends to recite the "fact" of the FDA's statements about adulteration in its November 2018 Warning Letter to ZHP, this assertion is inconsistent with Russ's testimony and, in any event, such testimony is not a proper expert opinion.

For all of these reasons, as set forth in Defendants' Motion and discussed further below, the Court should exclude Russ's proffered opinions in their entirety.

ARGUMENT

I. Russ's general qualifications to opine in other cases have no bearing on whether his analysis here was sufficiently rigorous to allow his opinions to reach the jury.

Russ's qualifications to render opinions in other litigations have no bearing on whether his methodology for arriving at opinions in this litigation is sufficiently

reliable. Plaintiffs' response correctly notes that Defendants did not challenge Russ's qualifications to opine generally on matters related to pharmaceutical manufacturing. (Response at 13). Plaintiffs mischaracterize the reasons Defendants seek to exclude Russ in this litigation in an attempt to compare his opinions to those which were offered in another case – but regardless, the fact that an expert has been permitted to testify in one litigation does not mean his failure to appreciate fundamental realities in another litigation can be ignored. Rule 702 and *Daubert* require that the expert's testimony in a specific case satisfy "a standard of evidentiary reliability," *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993) – the expert's general reputation and qualifications alone do not meet that requirement. *Cf. Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.").

Defendants' issue with Russ's opinions in this litigation is not his general experience – it is his methodology, the manner in which he has misapplied that limited experience to the facts of this litigation.

II. Plaintiffs' opposition ignores the fundamental issue with Russ's opinions in this case and merely parrots Russ's fallback explanations and opinions offered for the first time at deposition.

Russ's repeated statements that testing of ZHP's valsartan API by the Finished Dose Defendants "did not occur" is not merely his own ipse dixit, it is false. (*See*

Opposition at 20). Plaintiffs' Response parrots Russ's report, repeating statements that were shown at his deposition to be demonstrably untrue. (*See id.* at 20 (purporting to cite "ample evidence that Teva and Torrent did not conduct their own testing of ZHP's valsartan API")). For example, as documented by Teva's Annual Product Reviews, which Russ failed to review either prior to or at his deposition, Teva performed full specification testing on not just five batches but *every single batch* of ZHP's API manufactured under the prior process, as well as *every single batch* manufactured using ZHP's API manufactured under the new process, and documented the completion of that testing. (*See, e.g.*, Russ Dep. Exhs. 27 and 28, attached as Exhs. A and B). The failure to appreciate this type of core, critical information renders his analysis and all of his opinions as to the Finished Dose Defendants and specifically Teva unreliable and inadmissible. *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 797 (3d Cir. 2017) ("[A]ny step that renders [an expert's] analysis unreliable . . . renders [his or her] testimony inadmissible.").

Recognizing this error, Plaintiffs now bizarrely claim their expert can only rely on testing documented in the types of "raw" chromatography that was not subject to discovery, while wholly ignoring critical testing data that *was* produced. Plaintiffs' draft Requests for Production of Documents propounded in 2019 included a request for "Produce all documents or communications with regard to the actual or

attempted detection of impurities or contaminants in valsartan or any component or ingredient thereof, **including chromatographs, and intermediate testing**." (Draft Request No. 38 at 9, attached as Exh. C) (emphasis added). The Court heard argument on various macro-level discovery issues and ordered that finished dose manufacturers would be required to produce, at a minimum, not raw data but "**API testing results**, inspection reports, and communications regarding potential or actual nitrosamine contamination." (11/20/2019 Oral Opinion Deciding the Parties' "Macro" Issues Listed in the October 22, 2019 Order at 15:23-25, attached as Exh. D) (emphasis added). Accordingly, Plaintiffs withdrew the request for "raw" data such as chromatographs included in Request No. 38. *See* ECF No. 311-1 at 9 and ECF No. 328 at 8 (both showing Request No. 38 as "[WITHDRAWN]"); (12/11/2019 CMC Trans. 60:1-3, attached as Exh. E).

The Annual Product Reviews containing the results of chromatography testing for every single batch of ZHP's API used by Teva were produced on July 15, 2020, as part of the first rolling production of custodial and non-custodial documents responsive to Plaintiffs' discovery requests. (*See* 7.15.2020 Transmittal Letter, attached as Exh. F). Plaintiffs' Opposition characterizes the evidence Defendants point to as based on a "single document," "several" certificates of analysis, and a single witness transcript. (Opposition at 22). However, the comprehensive Annual Product Reviews and Certificates of Analysis were specifically included in this early

production in direct response not only to the approved Court-ordered RFPs but to Plaintiffs' request for prioritization of "*Finished Dose Manufacturing Quality Assurance Documents*" including "Validation Specifications associated with Valsartan API," "Certificate of Analyses associated with Valsartan API," and "OOS and OOT reports, and any root cause analyses, as a result of Valsartan API testing and/or validation." (5/7/2020 L. Hilton Ltr. to S. Goldberg, attached as Exh. G, at 2). This is precisely the information the Annual Product Reviews contain. Most notably, Russ declined to review *any* of this critical testing data, and instead leaped to the assumption (based on the fact he did not review any of the pertinent documents) that no testing whatsoever had occurred. (*See* Motion at 20).

Russ likewise failed to credit Dr. Jaiswal's testimony, which demonstrates that Torrent tested every batch of incoming API from ZHP, Exh. H ("Jaiswal Dep.") at 503:1-4 ("as part of . . . our own program, every batch was tested. I'm talking about the API batches being tested by us."), directly contradicting Russ's unfounded assertions. Plaintiffs attempt to excuse Russ's failure to consider this testimony by claiming Dr. Jaiswal offered contradictory testimony, which "Mr. Russ explicitly noted"[1] and chose not to credit. (Opposition at 25). However, the alleged

[1] Contrary to Plaintiffs' assertion, Russ did not "explicitly" identify a discrepancy in Dr. Jaiswal's testimony. (Opposition at 25). Russ actually testified that the "deposition testimony was somewhat muddled," "difficult to follow," and "appeared to" him "that no testing was performed." (Ex. B at 246:24-247:2). Russ's

"discrepancy" is based on Plaintiffs' mischaracterizations of Dr. Jaiswal's testimony. Dr. Jaiswal did testify that, from 2009 to 2015, Torrent did not specifically test for "genotoxic impurities." (*Id.* (quoting Opp. Ex. H [ECF 2331-1] at 212:5-8; 213:2-15)).[2] But Dr. Jaiswal clarified that "genotoxic impurity" is distinct from "a degradation impurity," and that degradation impurities were "always being monitored through the testing." (Jaiswal Dep. at 214:8-215:19; *see also id.* at 503:1-4 (confirming testing of every API batch).[3] Thus, Dr. Jaiswal consistently testified that Torrent tested every batch of incoming API from ZHP, and Plaintiffs' assertions otherwise are incorrect. *See* Jaiswal Dep. at 214:8-215:19, 503:1-4; Ex. G at ¶ 87 (Dr. Nagaich confirmed through a direct conversation with Dr. Jaiswal that "each incoming lot of API undergoes full testing as per the approved ANDAs

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testimony makes clear that he did not identify a discrepancy, but failed to accurately read and understand Dr. Jaiswal's testimony.

[2] Not testing for a "genotoxic impurity" is consistent with both Dr. Jaiswal's testimony and Dr. Nagaich's opinion that, because a finished does manufacturer does not have full knowledge of the API manufacturer's "route of synthesis, purification, and degradation pathways," they cannot conduct any meaningful "assessment to identify any trace level" genotoxic impurities. Ex. G at ¶ 85; *see also* Jaiswal Dep. at 192:16-21 ("As an ANDA holder, we never get the portion of the DMF. The ANDA holder is not able to understand . . . , which genotoxic impurities are supposed to be part of the specification").

[3] Plaintiffs' assertion that "Dr. Jaiswal appeared to change his answer between deposition days *when questioned on re-direct by Torrent's counsel*" misrepresents the record. (Opposition at 25 (emphasis added)). Instead, it was in response to Plaintiffs' counsel's direct examination that Dr. Jaiswal stated that, as he testified "yesterday," "every batch" of incoming ZHP API was "tested by" Torrent. Jaiswal Dep. at 501:15-503:4.

specifications and not just the identity testing").

Plaintiffs and Russ repeatedly claim that he reviewed "actual underlying records" which were somehow more detailed or reliable than the material ordered by this Court for production. (Opposition at 23-24). But Plaintiffs do not identify what these records are for a simple reason: Russ did not actually review anything to arrive at these opinions. (*See id.*; *see generally* Russ Rep.); *see also In re TMI Litig.*, 193 F.3d 613, 687 (3d Cir. 1999) (holding that opinions based on an expert's own ipse dixit rather than something more readily verifiable are inadmissible). The scope of discovery as to testing data was set over three years ago. In the intervening years Plaintiffs never once sought this data or expressed that the produced documents reflecting the chromatography testing performed on each and every batch of ZHP supplied API was insufficient for them or their experts. Even more crucially, it is plain from both Russ's report and his deposition testimony before being confronted with the testing data that he did not review unspecified underlying source documents to determine if testing took place – he merely concluded incorrectly that testing had not occurred, and prepared his report based on that assumption. (*See* Motion at 17-18). Plaintiffs' and Russ's attempt to move the goalposts and suggest that only additional documents, never within the scope of discovery set the by this Court or subsequently sought by Plaintiffs in discovery, could reliably support the well-documented test results set forth in Teva's Annual Product Reviews which Russ

ignored in his analysis is a last minute bait-and-switch. *See In re TMI Litig.*, 193 F.3d at 687.

As set forth in Defendants' Motion, once confronted at his deposition with the fact that the Finished Dose Defendants performed full testing on every single batch of ZHP's valsartan API they received, Russ tried to disavow his report which focused on the lack of testing and claimed that in fact his opinions were based on an absence of "comparative" analysis of chromatograms and the fact he did not see evidence that the Finished Dose Defendants analyzed "raw chromatography" data from ZHP. (*Id.* at 15-16). Unsurprisingly, Plaintiffs' Opposition makes the same argument, claiming that these two points are in fact the crux of Russ's analysis. But Plaintiffs' Opposition notably does not cite to Russ's report to demonstrate the basis for these opinions – because they are not found anywhere within his report.

Notably, Russ's report does not contain the word "comparative." (*See generally* Russ Rep.). As pointed out in Defendants' Motion, in the only two instances where Russ discusses any type of "comparison" testing that ought to be performed he was specifically discussing the comparison of *test results*, the exact type of analysis and comparison the Finished Dose Defendants performed by completing full specification testing of every single batch of ZHP's valsartan API. (*Id.* at 16). Similarly, "raw" chromatography data is mentioned only once in Russ's report, as an aside when discussing evidence he did not see in connection with the

Finished Dose Defendants' evaluation of ZHP's process change – a section where he also notes he did not see any evidence of testing performed on batches of ZHP's valsartan API, which he later was forced to concede had in fact occurred. (*See* Russ Rep. ¶¶ 76, 79).

Russ prepared and submitted an expert report based on his mistaken belief that testing of ZHP's valsartan API did not occur. He either ignored or was never shown key evidence produced nearly three years ago on a priority basis based on Plaintiffs' claim that documentary evidence of the chromatography testing performed on valsartan API was critical to their understanding of the case. As Russ himself stated in discussing the Finished Dose Defendants' oversight of their API supplier: "there's no other way to establish the reliability of test results if I don't look at any of the test results." (Russ Dep. at 137:1-2). Russ did not look at the test results. (Motion at 14). When confronted with this evidence, he pivoted to claiming that *documentary evidence of the full specification testing performed on every single batch of ZHP's valsartan API* was insufficient to determine if appropriate testing of the API in fact occurred. (*See id.* at 234:13-237:23). He tried to move the goalposts even further by concocting new justifications for his opinions purportedly based on "comparative testing" and evaluation of "raw chromatography" data, phrases which now appear throughout Plaintiffs' Opposition but are only referenced once, in passing, in Russ's report. The only discernible methodology connecting Russ's

report to his opinions offered at deposition and now in Plaintiffs Opposition is a desire for self-preservation.

In sum, Russ's entire expert report is predicated on his demonstrably false belief that the Finished Dose Defendants did not perform testing of ZHP's valsartan API. They did. The Court's gatekeeping function under Rule 702 requires keeping such malformed opinions from the jury. *See In re Zoloft*, 858 F.3d at 797.

III. Russ should not be permitted to offer expert opinions purporting to comment on Torrent's motivation, intent, and state of mind.

Plaintiffs do not contest the black letter law that "[e]xpert witnesses are not 'permitted to testify . . . regarding [a party's] intent, motive or state of mind, or evidence by which such state of mind may be inferred." *AztraZeneca LP v. Tap Pharm. Prods., Inc.*, 444 F. Supp. 2d 278, 293 (D. Del. 2006) (quoting *Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 443 (D. Del. 2004)). Instead, Plaintiffs attempt to re-characterize Russ's opinions as statements of "fact," (Opposition at 27-28), which ignores Russ's own admissions and misrepresents his opinions. *See* Ex. A at ¶ 106; Ex. B at 278:18-23.

Plaintiffs' argument that counsel's characterization of Russ's opinions "does not magically render them excludable," (Opposition at 28), ignores that *Russ himself admitted* that his opinions in paragraph 106 of his report are opinions on Torrent's motivation in accepting ZHP valsartan API. *See* Ex. B at 278:18-23 (Q. Are you offering anything about Torrent's motivation in accepting ZHP Valsartan API? THE

WITNESS: I certainly am in this paragraph [(106)].”). Russ’s own testimony about his improper motivation opinions “magically render[s] them excludable.”

Although Plaintiffs try to recast Russ’s opinions as statements of fact rather than opinions about Torrent’s motives and intent, a reading of the plain language of Russ’s report demonstrates that he is opining on Torrent’s “intent, motive, or state of mind.” (*AztraZeneca LP*, 444 F. Supp. 2d at 293). Russ opines as to *why* Torrent did not reject ZHP’s API: “Torrent could not afford to challenge or reject ZHP’s supply because ZHP was Torrent’s only supplier of valsartan API.” Ex. A at ¶ 106. He also opines as to *why* Torrent “sought out” ZHP as its API supplier: in order to reduce costs. *See id.* Russ further opines as to Torrent’s *state of mind* regarding ZHP’s API, asserting that Torrent experienced “undue pressure . . . to accept lower quality API” because ZHP was Torrent’s sole supplier of Valsartan API. *Id.* Finally, he opines as to *why* Torrent was “discouraged . . . from following expected cGMP practices”: because ZHP was Torrent’s sole supplier of valsartan API. *Id.* All of these opinions go beyond the mere recitation of “facts,” Opposition at 28, and improperly speak to Torrent’s intent, motivation, and state of mind in accepting ZHP’s valsartan API.[4] Each of these opinions should be excluded as improper. *See,*

[4] Plaintiffs’ argument that Russ’s improper opinions are admissible because they are tied to his experience or review of business records fails because these types of opinions “lie outside the bounds of expert testimony” and simply “describe[] ‘lay matters which a jury is capable of understanding and deciding without the expert’s

e.g., *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d at 545-47 & n. 38, 40 (excluding testimony that certain actions were motivated "by profit").

IV. Russ may not offer unsupported opinions about ZHP or that Teva or Torrent's VCDs were "adulterated" because they were not disclosed in his report.

Russ's opinion that ZHP's valsartan API and Teva and Torrent's VCDs were adulterated should be barred because this opinion: (1) was not properly disclosed; (2) is not based on reliable science; and (3) constitutes an improper legal conclusion.

First, Russ repeatedly admitted at his deposition that his report did not contain any opinions regarding ZHP or the adulteration of its valsartan API. (*See* Motion at 21-22 (citing Russ Dep. at 16:23-17:8; 278:12-16; 307:21-308:8; 313:6-14; 343:19-345:10).) Instead, Plaintiffs cite a single, summary passage in Russ's report that refers to "contamination of ZHP's valsartan API and cGMP failures at ZHP," without any supporting evidence or analysis, and generally noting that "the FDA found ZHP's valsartan API adulterated." (Opposition at 29 & Ex. A.) Such cursory statements come nowhere close to disclosing or supporting Russ's statement at his deposition – after being asked leading questions by Plaintiffs' counsel – that ZHP's valsartan API was adulterated at the time of sale because it "was identified to have a genotoxic impurity. For me, that is adulterated product. Period. End of sentence.

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help.'" *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546, 547 (S.D.N.Y. 2004).

No further discussion or evaluation needed." (Russ Dep. at 342:11-343:17.) Plaintiffs fail to cite a single case suggesting that such undisclosed opinions are admissible – and make no effort to distinguish the authorities cited by Defendants.

Second, even if Russ had properly disclosed the opinion that any product with a genotoxic impurity is adulterated "[p]eriod . . . [e]nd of sentence" (*id.*), he has no support for this assertion. Plaintiffs argue that Russ "bases this opinion on the indisputable *fact* that the FDA explicitly declared ZHP's valsartan adulterated" in the 2018 Warning Letter. (Opposition at 29 & Exhibit C.) But the 2018 Warning Letter does not say anything about ZHP's API being adulterated because of a genotoxic impurity and does not address Teva or Torrent whatsoever.[5] To the contrary, the FDA's statements on adulteration relate to its 2018 finding of nonconformance "to CGMP." (Opposition Exhibit C.) As a result, the 2018 Warning Letter does not provide support for Russ's entirely distinct adulteration opinion, which is instead based entirely on his own say-so.

Third, Plaintiffs fail to address this Court's prior ruling that whether and when ZHP's valsartan API was "adulterated" under FDA regulations and federal law are questions for the jury, not experts. *See* ECF No. 2261 at 93. Nor do they address the

[5] Furthermore, as Russ acknowledged at his deposition, the FDA never made a determination or statement of any kind that Teva's or Torrent's VCDs were adulterated. (Russ Dep. at 331:11-16.) Thus Russ's opinion that the finished dose was somehow vicariously adulterated constitutes an impermissible and baseless analytical leap.

binding Third Circuit precedent requiring that result. *See Berckeley Inv. Grp., Ltd. v. Colkitt,* 455 F.3d 195, 217 (3d Cir. 2006). While Plaintiffs assert that courts have permitted "experts, including Mr. Russ himself, to testify whether cGMP violations exist and the impact they would have" (Opposition at 31), Plaintiffs concede that "Russ is not offering an affirmative opinion on ZHP's cGMP deviations" (*id* at 30). Finally, Plaintiffs argument that Russ's adulteration opinion "is not a legal conclusion" because it simply recites "the *fact* that the FDA found that ZHP's valsartan was adulterated" (*id*. at 31), weighs against admission of this testimony, not in favor of it. For one thing, as noted above, the FDA's Warning Letter does not support Russ's adulteration opinion based on a "genotoxic impurity." And even if it did, it is well recognized that an expert may not simply "regurgitate factual information" with the false imprimatur of some special knowledge on the subject. *Pritchett v. I-Flow Corp.*, No. 09-cv-02433-WJM-KLM, 2012 WL 1059948, at *7 (D. Colo. Mar. 28, 2012); *see also Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 441-42 (D.N.J. 2009) (explaining that experts may not "simply summarize the facts and the depositions of others"). As a result, Russ should be precluded from recasting factual statements about adulteration in the 2018 Warning Letter as expert opinions.

CONCLUSION

For the foregoing reasons, Russ's opinions should be excluded.

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CERTIFICATE OF SERVICE

I hereby certify that on April 25, 2023, a copy of the foregoing document was servedon all counsel of record via CM/ECF.

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